

**REMARKS**

In the Official Action dated February 5, 2008, the Office issued a Restriction Requirement.

In this paper, Applicants have responded to the Restriction Requirement.

Applicants have amended claims 34 and 42 for purposes of expediting prosecution.

These amendments are all supported by the specification as filed. No new matter has been added. Applicants preserve the right to file continuing patent applications on any subject matter that has been cancelled from the claims.

### **Response to Restriction Requirement**

In response to the restriction requirement, Applicants elect with traverse Group II, Claims 1-36, directed to compounds/compositions and metabolites of formula I wherein two of B, D, and E are nitrogen. All of claims 1-43 are encompassed by the elected invention.

The Applicants traverse the restriction for the following reason: Claim 1 is generic. Accordingly, pursuant to MPEP §§ 803.02 and 809, the Applicants respectfully request the Office expand examination of the claims to the non-elected portion of the generic claims, which, in the present instance, is the full scope of all claims.

As stated in MPEP § 809,

There are a number of situations which arise in which an application has claims to two or more properly divisible inventions, so that a requirement to restrict the claims of the application to one would be proper, but presented in the same case are one or more claims (generally called 'linking' claims) which, if allowable, would require rejoinder of the otherwise divisible inventions. See MPEP § 821.04 for information pertaining to rejoinder practice. . . . The most common types of linking claims which, if allowable, act to prevent restriction between inventions that can otherwise be shown to be divisible, are (A) genus claims linking species claims . . . . The linking claims must be examined with, and thus are considered part of, the invention elected. When all claims directed to the elected invention are allowable, should any linking claim be allowable, the restriction requirement must be withdrawn. Any claims(s) directed to the non-elected invention(s), previously withdrawn from consideration, which depends from or requires all the limitations of the allowable linking claim must be rejoined and will be fully examined for patentability.

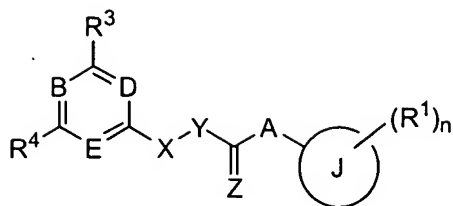
M.P.E.P. § 809 (emphasis added).

The applicants have the right to define what they regard as their invention, so long as their claims otherwise satisfy the statutory requirements. *In re Harnisch*, 206 U.S.P.Q. 300, 305 (C.C.P.A. 1980). Applicants have the right to have each claim examined on the merits. *In re Weber et al.*, 198 U.S.P.Q. 328, 331 (C.C.P.A. 1978). Restriction of the subject matter of a single claim in a patent application is therefore generally impermissible because it denies the applicant the right to have that claim examined on the merits. *Id.* As the court stated in *Weber*, if "a single claim is required to be divided up and presented in several applications, that claim would never be considered on its merits." *Id.* Accordingly, "it is improper for the Office to refuse to examine that which

applicants regard as their invention, unless the subject matter in a claim lacks unity of invention.” M.P.E.P. § 803.02.

The claims are written in Markush format. A Markush grouping is proper if the compounds in the Markush group share a single structural similarity and a community of properties (e.g., a common utility), such that the grouping is not repugnant to the principles of scientific classification. *Harnisch*, 206 U.S.P.Q. at 305; *Ex parte Brouard et al.*, 201 U.S.P.Q. 538, 540 (Bd. Pat. App. & Int. 1976). In other words, “unity of invention exists where compounds share a common utility, and (2) share a substantial structural feature essential to that utility.” M.P.E.P. § 803.02. The fact that the compounds in a Markush group may require different fields of search does not render the Markush group improper. *Brouard*, 201 U.S.P.Q. at 540. Also, where a Markush expression is applied only to a portion of a chemical compound, the propriety of the grouping is determined by consideration of the compound as a whole, and does not depend on there being a community of properties among the members of the Markush expression. *Id*; *Harnisch*, 206 U.S.P.Q. at 305; M.P.E.P. § 2173.05(h). In *Harnisch*, 206 U.S.P.Q. at 305, and as it is applied in *Ex parte Hozumi*, 3 U.S.P.Q.2d 1059 (Bd. Pat. App. & Int. 1984), the determinative factor for determining whether or not a Markush group is proper was held to be whether there existed “unity of invention,” or rather whether the claims were drawn to a collection of unrelated inventions. Specifically, the claims in *Harnisch* were drawn to a class of substituted coumarin compounds disclosed as being “useful as dyestuffs.” 206 U.S.P.Q. at 305. Accordingly, all of the claims had in common a functional utility related to a substantial structural feature disclosed as being essential to that utility.

Applicants submit that each of new claims 1-43 possesses unity of invention. First, all of the compounds share a common utility as p70S6 kinase inhibitors. Second, each of the compounds in the Markush group share common structural features that contribute to their activity. Each of the compounds share the following significant structural features:



where the ring containing B, D and E is a nitrogen containing heteroaryl moiety, and the J ring is an aromatic moiety. Accordingly, all of the compounds read upon claims that share common utility and structural features essential for that utility.

In view of the foregoing, the applicants submit that the claims are proper Markush claims and should be examined fully on their merits as generic linking claims for the elected group. To do otherwise would infringe on Applicants' "right to have each claim examined on the merits." *Weber*, 128 U.S.P.Q. at 331.

The proper procedure for examining Markush claims is provided in M.P.E.P. § 803.02:

A Markush-type claim may include independent and distinct inventions. ... In applications containing a Markush-type claim that encompasses at least two independent or distinct inventions, the examiner may require a provisional election of a single species prior to examination on the merits. ... Following election, the Markush-type claim will be examined fully with respect to the elected species and further to the extent necessary to determine patentability. If the Markush-type claim is not allowable, the provisional election will be given effect and examination will be limited to the Markush-type claim and claims to the elected species, with claims drawn to species patentably distinct from the elected species held withdrawn from further consideration.

\* \* \*

On the other hand, should the examiner determine that the elected species is allowable, the examination of the Markush-type claim will be extended. If prior art is then found that anticipates or renders obvious the Markush-type claim with respect to a *nonelected species*, the Markush-type claim shall be rejected and claims to the nonelected species held withdrawn from further consideration. The prior art search, however, will not be extended unnecessarily to cover all nonelected species. Should applicant, in response to this rejection of the Markush-type claim, overcome the rejection, as by amending the Markush-type claim to exclude the species anticipated or rendered obvious by the prior art, the amended Markush-type claim will be reexamined. The examination will be extended to the extent necessary to determine patentability of the Markush-type claim. In the event prior art is found during the reexamination that anticipates or renders obvious the amended Markush-type claim, the claim will be rejected and the

extent necessary to determine patentability of the Markush-type claim. In the event prior art is found during the reexamination that anticipates or renders obvious the amended Markush-type claim, the claim will be rejected and the action can be made final unless the examiner introduces a new ground of rejection that is neither necessitated by applicant's amendment of the claims nor based on information submitted in an information disclosure statement filed during the period set forth in 37 CFR 1.97(c) with the fee set forth in 37 CFR 1.17(p).

Pursuant to MPEP 803.02 and 809, the entire scope of the claims must be examined.

No fees are believed to be due in order to process this document and any paper attached. Should the U.S. Patent Office determine that an extension of time and/or other relief is required at this time, the Commissioner is authorized to charge the cost of such relief and/or fees to Deposit Account No. 50-1108, referencing EX04-066C-US.

Respectfully submitted,



Date: March 5, 2008

---

Robert L. Bernstein  
Attorney for Applicants  
Registration No. 46,020

Exelixis, Inc.  
210 East Grand Avenue  
Post Office Box 511  
South San Francisco, CA 94083-0511  
Direct Phone: (650) 837-7352  
Fax: (650) 837-8234